Drug Utilization Review Board Meeting Minutes, Open Session April 11, 2018		
Drug Utilization Review Board Meeting Location: DXC Technology, Building #283, Capital Room 6511 SE Forbes Ave, Topeka, KS 66619	**DUR Board Members Present** Moneeshindra Mittal, MD, Chair LaTonyua Rice, Pharm.D., CGP John Kollhoff, Pharm.D., Interim Chair(Phone) Tim Heston, DO Roger Unruh, DO James Backes, Pharm.D. **DHCF Staff Present** Annette Grant, RPh Roxanne Chadwell, Pharm.D., CSP Dr. Greg Lakin, D.O., Chief Medical Officer Carol Arace, Sr. Administrative Assistant **DXC Technology Staff Present** Karen Kluczykowski, RPh Ellen McCaffrey, BSN, MSN Kathy Kaesewurm, RN, BSN **HID Staff Present** Taylor DeRuiter, Pharm.D. **MCO Staff Present** Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh: Amerigroup	**Public Attendees:** Melissa Basil, Abbvie; Jim Baumann, Pfizer; Teresa Blair, Ipsen; Sheila Cedinere, Genzyne; Matt Conner, KDHE; Mary Jo DeFlorio, J&J; Brant DePinot, GSE; Cheryl Domanni, Savepta; Eric Gardner, Vertex; Lance Garner, DXC; Corinne Glock, KITE; Patrick Hecht, Avanir; Brant HildebranD, Gilead; Laura Hill, Abbvie; Rick Kegler, Otsuka; Karla Kenyon, Vartex; Cammille Kerr, Amgen; Meghan Kerrigan, Merck; Phil King, Pfizer; Donna Koehn, Bioverat; Liz Long, KDHE; Jason Lurk, Novo; Scott Maurice, B.I.; Parvoneh Navas, KITE; Alexandria Nugent, Avanir; Gregg Rasmusson, Vertix; Landon Sharpe, KU; Shefilyk, Novo; Liz Varner, KDHE; Marla Wiedenmann, NNI; Kim Witte, Avexis; Doug Wood, ViiV

TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Mittal called the meeting to order at 10:08am.	
A. Announcements	Ms. Grant introduced Dr. Lakin and Dr. Chadwell. Ms. Grant will bring Exondys 51® to the July meeting.	
II. Old Business **A. Review and Approval of October 11, 2017 Meeting Minutes**	**Board Discussion:**	Dr. Unruh moved to approve. Dr. Backes seconded the motion. The October 11, 2017 meeting minutes were approved unanimously.

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II. Old Business **B. Review and Approval of January 10, 2018 Meeting Minutes**	**Board Discussion:**	Tabled to the July 11, 2018 meeting.
III. New Business **A. Miscellaneous Items** 1. Fee-for-Service Retrospective Drug Utilization Review Topic Selections i. Topic Presentations	**Background:** The DUR Board will select topics for the two (2) RDUR intervention topics between April and August 2018. Topics presented by Dr. DeRuiter: 1. Development of osteoporosis and fracture risk associated with proton-pump inhibitors 2. Development of seizure risk associated with antipsychotics in patients with risk factors for seizure 3. Suicide risk associated with select antiepileptic medications 4. Therapeutic duplication of antidepressant agents **Board Discussion:** The Board felt that the first option was a top priority and the 4 topic was relevant to all physicians.	Dr. Backes moved to choose Topic 1 and Topic 4. Dr. Rice seconded the motion. The motion was approved unanimously.
III. New Business **A. Miscellaneous Items** 2. Fee-for-Service Retrospective Drug Utilization Review Outcomes Report i. Presentation	**Background:** The report from the 2017 Medicaid fee-for-service Drug Utilization Review interventions will be presented to show outcomes from the intervention program. Dr. DeRuiter presented the report to the DUR Board members.	Report presentation only.
B. New Preferred Drug List (PDL) Class 1. ADHD – Miscellaneous Type i. Non Preferred PDL PA Criteria	**Background:** At the March 2018 PDL meeting, the committee approved the addition of miscellaneous ADHD agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. **Public Comment:** None. **Board Discussion:** Ms. Grant mentioned that this PDL class was tabled at the April 2017 DUR meeting due to not having immediate-release products listed with the extended-release products. Immediate-release products are now listed.	Dr. Unruh moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.
C. Revised Prior Authorization (PA) Criteria 1. Anti-Constipation Agents (Trulance® [plecanatide]) i. Prior Authorization Criteria	**Background:** Trulance is a guanylate cyclase-C (GC-C) agonist indicated for the treatment of chronic idiopathic constipation in adults and is included in the Anti-Constipation Agents PA Criteria. The prior authorization criteria was last revised in April 2017. The prior authorization criteria are being revised to be consistent with other agents and ensure appropriate and cost-effective use.	Dr. Backes moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: April 9, 2014 Revised Dates: April 11, 2018; April 12, 2017; October 12, 2016 **CRITERIA FOR PRIOR AUTHORIZATION** Anti-Constipation Agents **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Linaclotide (Linzess®) Lubiprostone (Amitiza®) Plecanatide (Trulance®) **CRITERIA FOR LINACLOTIDE APPROVAL** (Must meet the following criteria): • Patient must have one of the following diagnoses: o chronic idiopathic constipation o irritable bowel syndrome (IBS) with constipation • Patient must be 18 years of age or older • Patient must have experienced an inadequate response after a 14-day trial of lactulose or polyethylene glycol (PEG-3350) at a maximum tolerated dose, OR have a documented intolerance or contraindication to both lactulose and polyethylene glycol (PEG-3350) • Patient must not have a known or suspected mechanical gastrointestinal obstruction **CRITERIA FOR LUBIPROSTONE APPROVAL** (Must meet the following criteria): • Patient must have one of the following diagnoses: o chronic idiopathic constipation o irritable bowel syndrome (IBS) with constipation o opioid-induced constipation with chronic, non-cancer pain • Patient must be 18 years of age or older • Patient must have experienced an inadequate response after a 14-day trial of lactulose or polyethylene glycol (PEG-3350) at a maximum tolerated dose, OR have a documented intolerance or contraindication to both lactulose and polyethylene glycol (PEG-3350) • Patient must not have a known or suspected mechanical gastrointestinal obstruction **CRITERIA FOR PLECANATIDE APPROVAL** (Must meet the following criteria): • Patient must have one of the following diagnoses: o Chronic idiopathic constipation o Irritable bowel syndrome with constipation • Patient must be 18 years of age or older • Patient must have experienced an inadequate response after a 14-day trial of lactulose or polyethylene glycol (PEG-3350) at a maximum tolerated dose, OR have a documented intolerance or contraindication to both lactulose and polyethylene glycol (PEG-3350) • Patient must not have a known or suspected mechanical gastrointestinal obstruction **LENGTH OF APPROVAL** 12 months **Notes:** • Linaclotide and plecanatide are contraindicated in patients less than 6 years of age due to the risk of serious dehydration. Avoid use in patients 6-17 years of age. **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior	**Background:**	Dr. Unruh moved to table.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Authorization (PA) Criteria 2. Botulinum Toxins i. Revised PA Criteria	Botulinum toxins carry multiple FDA-approved indications for use. Prior authorization criteria were last revised in October 2016. The prior authorization criteria are being revised to be consistent with other agents and ensure appropriate and cost-effective use. **Public Comment:** Teresa Blair with Ipsen Biopharmaceuticals spoke on behalf of IncobotulinumtoxinA. Ms. Blair asked the Board to consider not designating neurologists in the criteria 'must be prescribed by or in consultation with…' and if the Board does, to please consider other specialists to be listed. **Board Discussion:** The Board requested additional information for clarification to elevate possible undue burden for prescribers and possibly to add other specialists if they meet the proper training. Dr. DeRuiter noted he would bring the data to the next DUR meeting.	Dr. Kollhoff seconded the motion. The motion was approved unanimously.
C. Revised Prior Authorization (PA) Criteria 3. CFTR Modulators i. Revised PA Criteria	**Background:** Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are indicated for the treatment of cystic fibrosis (CF). Prior authorization criteria was initially approved in July 2017. Since that time, Symdeko has been FDA-approved for the treatment of patients 12 years of age or older. The prior authorization criteria are being revised to include the new agent to ensure appropriate and cost-effective use.	Dr. Unruh moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: October 14, 2015 Revised Dates: April 11, 2018; July 26, 2017 **CRITERIA FOR PRIOR AUTHORIZATION** CFTR (cystic fibrosis transmembrane conductance regulator) Modulators **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Ivacaftor (Kalydeco®) Lumacaftor/ivacaftor (Orkambi®) Tezacaftor/Ivacaftor (Symdeko™) **CRITERIA FOR KALYDECO:** (must meet all of the following) • Patient must have a diagnosis of cystic fibrosis (CF) • Patient must be at least 2 years old, • Patient must have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data o If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use • Patient must not be homozygous for the F508del mutation in the CFTR gene • Patient must not be on another CFTR modulator concurrently **LENGTH OF APPROVAL:** 12 months **CRITERIA FOR ORKAMBI:** (must meet all of the following) • Patient must have a diagnosis of cystic fibrosis (CF) • Patient must 6 years of age or older • Patient must be homozygous for *F508del* mutation in the CFTR gene o If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. • Patient must not be on another CFTR modulator concurrently **LENGTH OF APPROVAL:** 12 months **CRITERIA FOR SYMDEKO:** (must meet all of the following) • Patient must have a diagnosis of cystic fibrosis (CF) • Patient must be at least 12 years old • One of the following must be met: o Patient must be homozygous for *F508del* mutation in the CFTR gene o Patient must have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay data o If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use • Patient must not be on another CFTR modulator concurrently **LENGTH OF APPROVAL:** 12 months **Notes**: Providers may be referred to the Cystic Fibrosis Foundation website for information regarding genetic testing to patients with a confirmed diagnosis of cystic fibrosis: http://www.cff.org/treatments/Therapies/Kalydeco/#Is_Kalydeco_only_for_G551D.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Public Comment: Karla Kenyon with Vertex offered to answer questions from the Board. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 4. Somatropin Products i. Revised PA Criteria	**Background:** Somatropin products are used for several indications in both children and adults. Prior authorization criteria were last revised in July 2017. Since then, Norditropin has been FDA-approved for the treatment of Prader-Willi Syndrome and Zomacton has been FDA approved for growth hormone deficiency in adults. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Unruh moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.

APPROVED PA Criteria

Initial Approval: September 14, 2005
Revised Dates: April 11, 2018; July 26, 2017; July 8, 2015; July 9, 2014
September 12, 2007; May 10, 2006

CRITERIA FOR PRIOR AUTHORIZATION

Somatropin Products

PROVIDER GROUP Pharmacy
MANUAL GUIDELINES All dosage forms of the following drugs require prior authorization: Somatropin (Genotropin®, Humatrope®, Norditropin®, Nutropin®, Omnitrope®, Saizen®, Tev-Tropin®, Zomacton®)

Prior Authorization for Initiation of Growth Hormone in Children

CRITERIA FOR PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD): (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request and at least one of the following criteria is met:
  - Child has severe short stature with height standard deviation score (SDS) more than 3 SDS below the mean for chronological age and sex
  - Height more than 1.5 SDS below the mid-parental height
  - Child has moderate growth retardation with height more than 2 SDS below the mean and a height velocity over 1 year more than 1 SDS below the mean for chronological age, or a decrease in height SDS of more than 0.5 over 1 year in children over 2 years of age;
  - In the absence of short stature, a height velocity more than 2 SDS below the mean over 1 year or more than 1.5 SDS sustained over 2 years
  - Child has decreasing growth rate combined with a predisposing condition such as previous cranial irradiation or tumor
  - Child exhibits evidence of other pituitary hormone deficiencies or signs of congenital GHD (hypoglycemia, microphallus, prolonged jaundice, traumatic delivery)
- Normal thyroid function tests (TSH 0.4-4.0 mIU/L)
- Failure to respond to 2 growth hormone secretagogues with peak < 10ng/mL
  - MRI required for neonatal growth hormone deficiency AND those with peak < 5ng/mL
  - EXCEPTION: neonatal hypopituitarism/hypoglycemia where either GH peak < 10ng/mL during documented hypoglycemia is indication of GH deficiency OR documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects)
- Request should be for any of the following:
  - Tev-Tropin®, Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Saizen®, Genotropin®, Zomacton®

CRITERIA FOR PANHYPOPITUITARISM: (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have documented deficiencies of AT LEAST one pituitary hormone; TSH, ACTH, LH/FSH, ADH.
  - Deficiencies in thyroid and Cortisol must be treated before performance of the GH stimulation test.
- Degree of GH deficiency must be documented by response to 2 GH secretagogues:
  - Patient must be on stable doses of other replacement hormones before performing stimulation tests.
  - Normal thyroid levels documented before testing (TSH 0.4-4.0 mIU/L).
  - < 5ng/mL = severe and < 10ng/mL = deficiency
  - EXCEPTION: – neonatal hypopituitarism/hypoglycemia where either GH peak < 10ng/ml during documented hypoglycemia is indication of GH deficiency or documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects). Deficiency can be documented by failure to respond to secretagogues but is not required

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	CRITERIA FOR CHRONIC RENAL INSUFFICIENCY (CRI): (must meet all of the following)
	• Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
	• Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
	• Diagnosis must be presented upon request.
	• Patient must have a confirmed diagnosis of CRI by a Pediatric Nephrologist.
	• Height velocity < 25th percentile for age:
	  o Requires at least 6 months of growth data
	  o Growth curve must be submitted
	• Request must be for one of the following:
	  o Nutropin®
	CRITERIA FOR TURNER OR NOONAN SYNDROME: (must meet all of the following)
	• Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
	• Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
	• Diagnosis must be presented upon request.
	• Patient must have a confirmed diagnosis of Turner or Noonan syndrome by karyotype.
	• Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
	• Height velocity < 25th percentile for age or height < 5th percentile:
	  o Requires at least 6 months of growth data
	  o Growth curve must be submitted
	• Request must be for one of the following:
	  o Turner Syndrome
	  ▪ Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Genotropin®
	  o Noonan Syndrome
	  ▪ Norditropin®
	CRITERIA FOR PRADER-WILLI SYNDROME (PWS): (must meet all of the following)
	• Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
	• Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
	• Diagnosis must be presented upon request.
	• Patient must have a confirmed diagnosis of PWS by a Geneticist.
	• Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
	• DEXA scan for body composition
	• Absence of obstructive sleep apnea by sleep study or treated obstructive sleep apnea
	• Height velocity < 25th percentile for age or height < 5th percentile:
	  o Requires at least 6 months of growth data
	  o Growth curve must be submitted
	• Request must be for one of the following:
	  o Omnitrope®, Genotropin®, Norditropin®
	
	CRITERIA FOR SMALL FOR GESTATIONAL AGE (SGA): (must meet all of the following)
	• Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
	• Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
	• Diagnosis must be presented upon request.
	• Birth weight of less than 2,500 g at a gestational age of more than 37 weeks or a birth weight or length below the 3rd percentile for gestational age.
	• Failure to manifest catch-up growth to reach normal height range by age 2
	• Request must be for one of the following:	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria o Omnitrope®, Genotropin®, Norditropin® **Length of Approval:** 6 months **Prior Authorization for Renewal of Growth Hormone in Children** • Renewal of GH in children: o History and physical notes, and growth curve from pediatric endocrinologist dated within 6 months of request o Documented catch-up growth unless at target height percentile • Rationale for discontinuing GH therapy, only one of the following must be met: o Growth velocity < 2cm/year while on GH therapy ▪ There are persistent and uncorrectable problems with adherence to GH treatmentCompliance is defined as greater than or equal to 85% adherence to regimen (no more than one missed dose per week on average) ▪ Prescriber must attest to patient adherence, and prescription claims data may be used to verify adherence o Recommendations of treating pediatric nephrologist or endocrinologist due to changes in underlying conditions o If there is poor response to treatment, generally defined as an increase in growth velocity of less than 50% from baseline, in the first year of therapy. In children with PWS, evaluation of response to therapy should also take into account whether body composition (i.e., ratio of lean to fat mass) has significantly improved o Evidence of epiphyseal closure o Expected final adult height has been reached, as defined by reaching the calculated mid-parental height* or reaching the 25th percentile of the adult height based on sex**, whichever comes first **Length of Renewal:** 12 months **Prior Authorization for Growth Hormone in Adults** • Must be prescribed by or in consultation with an endocrinologist • Patient must have one of the following: o diagnosis of pituitary insufficiency confirmed by growth hormone stimulation test (< 5ng/mL serum concentration) and below normal IGF-1/IGFBP3 (see table for normal ranges) o diagnosis of panhypopituitarism including those with surgical or radiological eradication of pituitary confirmed by MRI or CT scan • Member has a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease-specific 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire • If non-preferred Growth Hormone medication is being requested, then the Growth Hormone PDL form must also be completed and submitted for processing. Clinical Reviewers will follow established PDL guidelines. (Please note that for non-preferred drug requests the documentation must meet established clinical and PDL criteria to be approved. For requests for preferred drug then only the established clinical criteria must be met.) • Request must be for one of the following: o Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Saizen®, Genotropin®, Zomacton® **Length of Approval:** 12 months Notes: • Mid parental height calculation: o <u>For Boy:</u> ▪ In inches: (Father's Height + Mother's Height + 5) / 2 ▪ In cm: (Father's Height + Mother's Height + 13) / 2 o <u>For Girl</u> ▪ In inches: (Father's Height - 5 + Mother's Height) / 2	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria ▪ In cm: (Father's Height - 13 + Mother's Height) / 2 o 25th percentile of adult height based on CDC growth chart is defined as 5'8'' (172 cm) for boys and 5'2.5'' (159 cm) for girls • The use of growth hormone for diagnosis of idiopathic short stature (ISS) is not considered medically necessary and therefore is not covered under the Pharmacy benefit. This is an administrative denial and the review is not based upon medical necessity. **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 5. Humira® (adalimumab) i. Revised PA Criteria	**Background:** Humira is an immunomodulator indicated for the treatment of several disorders. Prior authorization criteria were last revised in October 2017. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use. APPROVED PA Criteria Policy/Clarification Number: E2003-053 Initial Approval: November 9, 2005 Revised Dates: April 11, 2018; October 11, 2017; April 12, 2017; October 12, 2016 April 13, 2016; January 13, 2016; January 14, 2015 April 10, 2013; June 15, 2011; January 12, 2011 November 12, 2008; July 9, 2008; March 12, 2008 CRITERIA FOR PRIOR AUTHORIZATION Adalimumab (Humira®, Cyltezo™, Amjevita®) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: All dosage forms of the following drugs require prior authorization: Adalimumab (Humira®) Adalimumab-adbm (Cyltezo™) Adalimumab-atto (Amjevita®) CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following) • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Patient must be on concomitant methotrexate with dosing of adalimumab 40 mg every other week. For patients contraindicated or not able to take concomitant methotrexate, dosing frequency may be increased to adalimumab 40 mg every week. CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA): (must meet all of the following) • Patient must have a diagnosis of juvenile idiopathic arthritis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 2 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days CRITERIA FOR PSORIATIC ARTHRITIS (PsA): (must meet all of the following) • Patient must have a diagnosis of psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days CRITERIA FOR ANKYLOSING SPONDYLITIS (AS): (must meet all of the following) • Patient must have a diagnosis of ankylosing spondylitis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days CRITERIA FOR CROHN'S DISEASE (CD): (must meet all of the following) • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days	Dr. Heston moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Policy/Clarification Number: E2003-053 • Patient must have experienced an inadequate response after a trial of a conventional Crohn's disease therapy (see attached table) at a maximum tolerated dose, OR have a documented intolerance or contraindication to the conventional Crohn's disease therapies (see attached table). **CRITERIA FOR PEDIATRIC CROHN'S DISEASE (CD) (HUMIRA ONLY):** (must meet all of the following) • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 6 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Patient must have experienced an inadequate response after a trial of corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate at a maximum tolerated dose, OR have a documented intolerance or contraindication to corticosteroids and immunomodulators. **CRITERIA FOR ULCERATIVE COLITIS (UC):** (must meet all of the following) • Patient must have a diagnosis of ulcerative colitis • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Patient must have experienced an inadequate response after a trial of a conventional ulcerative colitis therapy (see attached table) at a maximum tolerated dose, OR have a documented intolerance or contraindication to the conventional ulcerative colitis therapies (see attached table). **CRITERIA FOR PLAQUE PSORIASIS (PS):** (must meet all of the following) • Patient must have a diagnosis of plaque psoriasis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has taken an oral agent for the treatment of plaque psoriasis (see attached table) **OR** patient is a candidate for systemic therapy or phototherapy **CRITERIA FOR HIDRADENTITIS SUPPURATIVA (HS) (HUMIRA ONLY):** (must meet all of the following) • Patient must have a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or III or Acne Inversa Severity Index [AISI] score of ≥ 10) • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR UVEITIS (HUMIRA ONLY):** (must meet all of the following) • Patient must have a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis • Must be prescribed by or in consultation with an ophthalmologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **LENGTH OF APPROVAL** 12 months **Public Comment:** None.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Board Discussion: None.	
C. Revised Prior Authorization (PA) Criteria 6. Mavyret™ (glecaprevir/pibrentasvir) i. Revised PA Criteria	**Background:** Mavyret is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). The prior authorization criteria was initially approved in October 2017. The prior authorization criteria are being revised to include criteria for treatment of refractory hepatitis C.	Dr. Backes moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

APPROVED PA Criteria

Initial Approval: October 11, 2017
Revised Dates: April 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

glecaprevir/pibrentasvir (Mavyret™)

PROVIDER GROUP Pharmacy
MANUAL GUIDELINES The following drug requires prior authorization:
Glecaprevir/Pibrentasvir (Mavyret™)

CRITERIA FOR NON-REFRACTORY, INITIAL APPROVAL (must meet all of the following):
Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to the duration listed below)

- Patient must have a diagnosis of chronic hepatitis C virus (HCV)
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not be on a concurrent direct acting hepatitis C agent or ribavirin
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 3 tablets per day
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3 or greater)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C)
- Patient must not be concurrently prescribed atazanavir or rifampin
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment

CRITERIA FOR REFRACTORY, INITIAL APPROVAL: (must meet all of the following)

- Patient must meet all criteria for non-refractory, initial approval of glecaprevir/pibrentasvir (above)
- MCO claims data must indicate greater than or equal to 90% adherence to the previous direct-acting antiviral regimen (the MCO reviewer should verify this by the MCO claims data)
- Prescriber has submitted documentation showing that the patient has a documented presence of detectable HCV RNA at/up to 12 weeks after the last treatment was given
  - An assessment of viral response, including documentation of Sustained Viral Response (SVR), using an FDA-approved quantitative or qualitative nucleic acid test (NAT) with a detection level of greater than (>) 25 IU/mL at/up to 12 weeks after the last treatment was given (https://www.hcvguidelines.org/evaluate/when-whom)

CRITERIA FOR RENEWAL (must meet all of the following):

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents
- Must meet one of the following:
  - Genotype 1 (one of the following):
    - Treatment naïve AND without cirrhosis – **8 weeks total duration**
    - Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration**

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria ▪ Without cirrhosis AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **8 weeks total duration** ▪ With compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **12 weeks total duration** ▪ Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with a regimen containing an NS3/4A PI* without prior treatment with an NS5A inhibitor – **12 weeks total duration** ▪ Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with a regimen containing an NS5A inhibitor** without prior treatment with an NS3/4A PI – **16 weeks total duration** * Simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin **ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin o Genotype 2, 4, 5, or 6 (one of the following): ▪ Treatment naïve AND without cirrhosis – **8 weeks total duration** ▪ Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration** ▪ Without cirrhosis AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **8 weeks total duration** ▪ With compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **12 weeks total duration** o Genotype 3 (one of the following): ▪ Treatment naïve AND without cirrhosis – **8 weeks total duration** ▪ Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration** ▪ Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **16 weeks total duration** **LENGTH OF APPROVAL FOR GLECAPREVIR/PIBRENTASVIR:** 4 weeks Notes: • The proximate goal of HCV therapy is Sustained Virologic Response (SVR) (virologic cure), defined as the continued absence of detectable HCV RNA for at least 12 weeks after completion of therapy. SVR is a marker for cure of HCV infection and has been shown to be durable in large prospective studies in more than 99% of patients followed-up for ≥5 years (Swain, 2010); (Manns, 2013). Assessment of viral response, including documentation of SVR, requires use of an FDA-approved quantitative or qualitative nucleic acid test (NAT) with a detection level of less than or equal to (≤) 25 IU/mL (https://www.hcvguidelines.org/evaluate/when-whom).	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Public Comment: Laura Hill with Abbvie spoke on behalf of Mavyret™ requesting the DUR Board to lower the Metavir score, as other states are doing this and patients could be treated sooner. **Board Discussion:** Ms. Grant mentioned that the State is looking into possibly lowering the Metavir score, but is not able to make that decision at this time. There is data needed and a financial impact that the State would need to account for first. No final decisions have been made yet.	
C. Revised Prior Authorization (PA) Criteria 7. Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir) i. Revised PA Criteria	**Background:** Vosevi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). The prior authorization criteria was last reviewed in October 2017. The prior authorization criteria are being revised to be consistent with other agents, include criteria for treatment of refractory hepatitis C, and ensure appropriate and cost-effective use.	Dr. Backes moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

	APPROVED PA Criteria
	
	Initial Approval: July 26, 2017
	Revised Dates: April 11, 2018; October 11, 2017
	
	CRITERIA FOR PRIOR AUTHORIZATION
	
	sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)
	
	PROVIDER GROUP Pharmacy
	
	MANUAL GUIDELINES The following drug requires prior authorization:
	Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi™)
	
	CRITERIA FOR NON-REFRACTORY, INITIAL APPROVAL OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR: (must meet all of the following)
	
	Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of Sofosbuvir/Velpatasvir/Voxilaprevir therapy total)
	
	• Patient must have a diagnosis of chronic hepatitis C (CHC) (hepatitis C virus [HCV])
	• Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
	• Patient must not have severe renal impairment (eGFR<30mL/min/1.73m^2) or currently require hemodialysis
	• Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
	• Patient must be 18 years of age or older
	• Patient must not be on concurrent direct acting hepatitis C agents
	• Patient must meet one of the following:
	  o Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
	  o Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir WITHOUT an NS5A inhibitor
	• Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
	• Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
	• Dose must not exceed 1 tablet per day
	• Patient must have one of the following:
	  o Advanced fibrosis (Metavir F3)
	  o Compensated cirrhosis (Child-Pugh A)
	  o Organ transplant
	  o Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
	  o Proteinuria
	  o Nephrotic syndrome
	  o Membranoproliferative glomerulonephritis
	• Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with sofosbuvir/velpatasvir/voxilaprevir therapy
	• For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
	• Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment
	• Patient must not be on concurrent rifampin
	• Patient should not be on concurrent:
	  o P-gp inducers
	  o Moderate to potent CYP2B6, 2C8, or 3A4 inducers
	  o Amiodarone (if alternative, viable treatment options are unavailable, cardiac monitoring is recommended)	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria **CRITERIA FOR REFRACTORY, INITIAL APPROVAL OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR:** (must meet all of the following) • Patient must meet all criteria for non-refractory, initial approval of sofosbuvir/velpatasvir/voxilaprevir (above) • MCO claims data must indicate greater than or equal to 90% adherence to the previous direct-acting antiviral regimen (the MCO reviewer should verify this by the MCO claims data) • Prescriber has submitted documentation showing that the patient has a documented presence of detectable HCV RNA at/up to 12 weeks after the last treatment was given o An assessment of viral response, including documentation of Sustained Viral Response (SVR), using an FDA-approved quantitative or qualitative nucleic acid test (NAT) with a detection level of greater than (>) 25 IU/mL at/up to 12 weeks after the last treatment was given (https://www.hcvguidelines.org/evaluate/when-whom) **RENEWAL CRITERIA FOR SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR:** • Prescriber must document adherence by patient of greater than or equal to 90% **LENGTH OF APPROVAL FOR SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR:** 4 weeks for a **total of 12 weeks of treatment** Notes: • NS5A inhibitors: daclatasvir, elbatasvir, ledipasvir, ombitasvir, velpatasvir • Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor. • The proximate goal of HCV therapy is Sustained Virologic Response (SVR) (virologic cure), defined as the continued absence of detectable HCV RNA for at least 12 weeks after completion of therapy. SVR is a marker for cure of HCV infection and has been shown to be durable in large prospective studies in more than 99% of patients followed-up for ≥5 years (Swain, 2010); (Manns, 2013). Assessment of viral response, including documentation of SVR, requires use of an FDA-approved quantitative or qualitative nucleic acid test (NAT) with a detection level of less than or equal to (≤) 25 IU/mL (https://www.hcvguidelines.org/evaluate/when-whom). **Public Comment:** Public comment was addressed for agenda items 6 & 7 during agenda item #6. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 8. Nuedexta® (dextromethorphan/quinidine) i. Revised PA Criteria	**Background:** Nuedexta is a combination product for the treatment of pseudobulbar affect (PBA). Dextromethorphan stimulates sigma-1 receptors and inhibits NMDA receptors, and quinidine inhibits dextromethorphan metabolism increasing bioavailability. The criteria was last revised in October 2011. The prior authorization criteria are being revised to be consistent with other agents and ensure appropriate and cost-effective use.	Dr. Heston moved to approve as amended. Dr. Kollhoff seconded the motion. The motion was approved as amended unanimously.

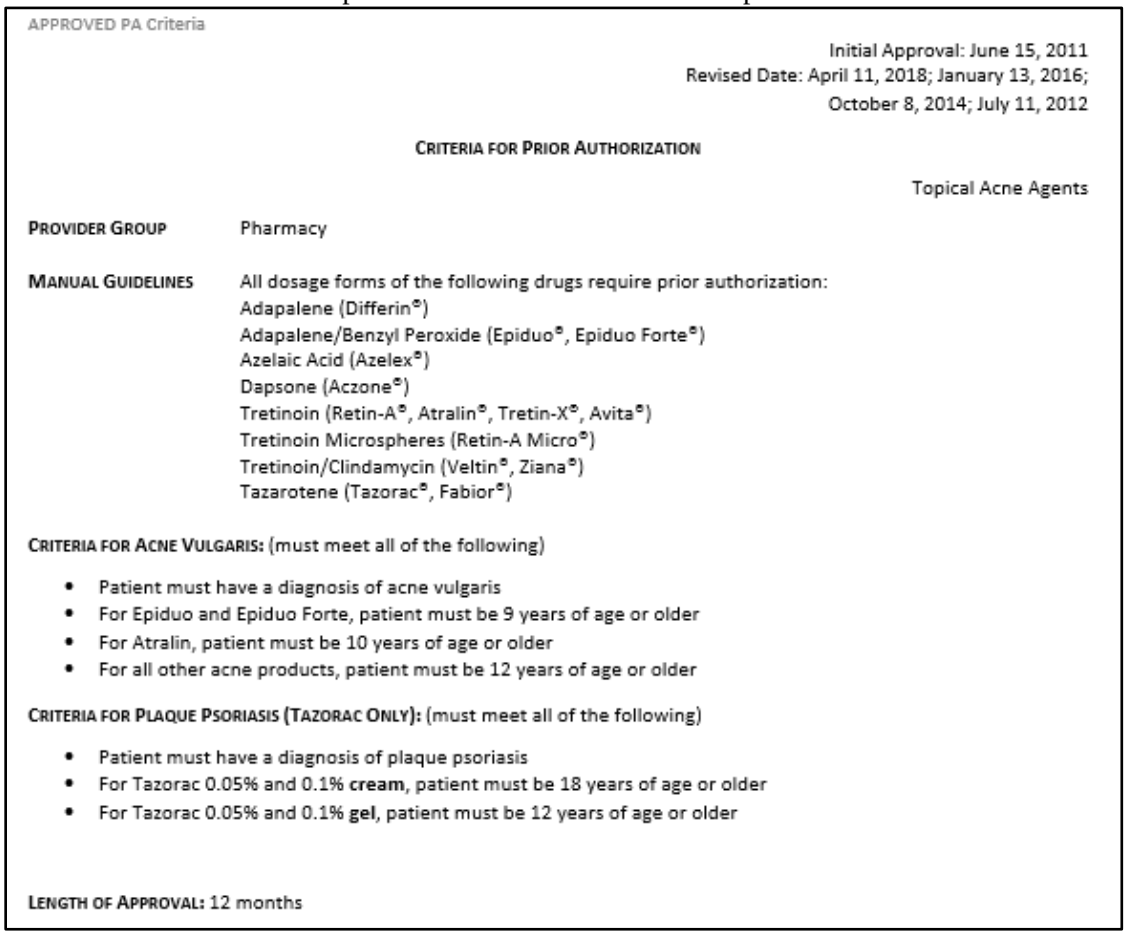
TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Effective Date: April 13, 2011 Revised Date: April 11, 2018; October 12, 2011 **CRITERIA FOR PRIOR AUTHORIZATION** Dextromethorphan/Quinidine (Nuedexta®) **PROVIDER GROUP:** Pharmacy **MANUAL GUIDELINES:** All dosage forms of the following drugs require prior authorization: Dextromethorphan/Quinidine (Nuedexta®) **CRITERIA FOR PRIOR AUTHORIZATION:** (must meet all of the following) • Patient must be 18 years of age or older • Patient must have a diagnosis of pseudobulbar affect (PBA) • Patient does not have history of complete atrioventricular (AV) block without a pacemaker, congenital long QT syndrome, or heart failure • Patient is not currently receiving monoamine oxidase inhibitor therapy or discontinued their use in the last 14 days • Patient is not currently receiving any medications containing quinine, quinidine, or mefloquine • Patient is not currently receiving pimozide or thioridazine Dose must not exceed dextromethorphan 40 mg/quinidine 20 mg (2 capsules) per day **LENGTH OF APPROVAL:** 6 months **Public Comment:** Alexandria Nugent with Avanir Pharmaceuticals spoke on behalf of Nuedexta®. **Board Discussion:** Due to the wide use of this agent, the Board recommended removing the 'Must be prescribed by or in consultation with a neurologist' criteria.	
C. Revised Prior Authorization (PA) Criteria 9. Opioids i. Revised PA Criteria	**Background:** This criteria covers all short and long-acting opioids. The criteria was initially approved in January 2018. Since that time, a new short-acting opioid product containing benzhydrocodone has been FDA-approved for treatment of pain. The prior authorization criteria are being revised to include the new agent, ensure appropriate use based upon the FDA-approved labeling information, CDC guidelines, CMS Best Practices, and input from an internal team composed of members from DXC, KDHE, KDADS, and the MCOs, and to be consistent with similar agents.	Dr. Backes moved to approve as amended. Dr. Heston and Dr. Unruh seconded the motion. The criteria was approved as amended unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA CRITERIA Initial Approval: January 10, 2018 Revised Dates: April 11, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Opioid Products Indicated for Pain Management **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: **Long-Acting Opioids:** **Includes both brand and generic versions of the listed products unless otherwise noted:** Buprenorphine (Butrans, Belbuca) Fentanyl transdermal (Duragesic) Hydrocodone extended-release (Zohydro ER, Hysingla ER, Vantrela ER) Hydromorphone extended-release (Exalgo) Methadone Morphine controlled-release/extended-release (Kadian ER, Avinza, MS Contin, Oramorph, Arymo ER) Morphine/Naltrexone (Embeda) Oxycodone extended-release (OxyContin) Oxycodone extended-release (Xtampza ER) Oxycodone/Naloxone (Targiniq ER) Oxycodone/Naltrexone (Troxyca ER) Oxymorphone extended-release (generic non-crush resistant) Oxymorphone extended-release (Opana ER-crush resistant) Tapentadol extended-release (Nucynta ER) Tramadol extended-release (Ultram ER, Ryzolt) **Short-Acting Opioids:** **Includes both brand and generic versions of the listed products unless otherwise noted:** (All salt forms, single and combination ingredient products, and all brand and generic formulations of the following): Benzhydrocodone Codeine Dihydrocodeine Fentanyl Hydrocodone Hydromorphone Levorphanol Tartrate Meperidine Morphine Oxycodone Oxymorphone Pentazocine/Naloxone Tapentadol Tramadol **1. CRITERIA FOR OPIOID USE IN DIAGNOSIS OF CANCER, SICKLE CELL DISEASE, HOSPICE/PALLIATIVE CARE** • Must meet one of the following: o Patient is being treated for pain related to active cancer diagnosis. o Patient is being treated for sickle cell disease. o Patient is receiving hospice or palliative care. o Fentanyl patches are only approved for patients with a diagnosis of cancer or palliative care related pain. o Trans-mucosal Immediate Release Fentanyl (TIRF) products are only approved for patients with a diagnosis of cancer. o Methadone is only approved for diagnosis of terminal cancer pain. • Prescriber must have a KMAP ID. • Prescriber must attest that they are enrolled in the REMS program to prescribe for TIRF products. **Approval Duration:** 12 months	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA CRITERIA **2. CRITERIA FOR OPIOID USE IN NON CANCER, NON SICKLE CELL DISEASE, NON HOSPICE/PALLIATIVE CARE FOR ACUTE PAIN (For these PA requests, acute pain is defined as patients with < 90 days of opioid medication in the past 120 days. Methadone and fentanyl products are not covered for acute pain)** • No prior authorization is required for prescriptions equal to or for no more than a cumulative 14 day supply of opioids in the last 60 days within allowed limits. o Maximum of 7 day supply is allowed per fill. o Cumulative opioid dose must not exceed 90 MME per day. o Drug must not exceed maximum FDA approved dosage. o Drug requested must not be a long-acting opioid. o Prescriber must have a KMAP ID. • Prior authorization is required to exceed 14 day supply of opioid medication in last 60 days (must meet all of the following): o Patient has attempted treatment with at least 2 non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) in the last 90 days, unless contraindicated. o Prescriber must have a KMAP ID. o Cumulative opioid dose must not exceed 90 MME per day or maximum FDA approved dosage. o Drug requested is not a long-acting opioid. o Prescriber attests to the following: ▪ Non-pharmacological treatment has been tried and/or is currently being used (e.g., exercise, cognitive behavior therapy, or interventional treatment) ▪ Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program (PDMP) a.k.a K-TRACS. ▪ Treatment duration and goals are defined with the patient and in the medical record. ▪ Patient has been screened for substance abuse/opioid dependence. ▪ If patient is concurrently on a CNS depressant (e.g., benzodiazepines), prescriber has reviewed and will address the increased risk of respiratory depression with the patient. ▪ Patient has been screened for depression or other mental health illness. • If patient is positive for depression, patient is receiving either pharmacological or nonpharmacological treatment. **Renewal Criteria:** o Attempting to taper dose/frequency **or** o Documentation in medical record the reason for not tapering the dose/frequency **Approval Duration:** 30 days; Maximum of 2 renewals (90 days total, not including the initial 14 days of treatment before PA is required) **3. CRITERIA FOR OPIOID USE IN NON CANCER, NON SICKLE CELL DISEASE, NON HOSPICE/PALLIATIVE CARE FOR CHRONIC PAIN (For these PA requests, chronic pain is defined as patients with ≥90 days of opioid medication in the past 120 days Methadone and fentanyl products are not covered for chronic pain)** • Prior authorization is required to exceed 90 day supply of opioid claims (must meet all of the following): o Patient has attempted treatment with at least 2 non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants), unless contraindicated. o Prescriber must have a KMAP ID. o Patient must not be taking more than one long-acting & one short-acting opioid analgesics, concurrently. o Prescriber attests to the following: ▪ Non-pharmacological treatment has been tried and/or is currently being used. (e.g., exercise, cognitive behavior therapy, or interventional treatment). ▪ Prescriber has reviewed controlled substance prescriptions in PDMP (K-TRACS). o Documentation of treatment duration and treatment goals to include: ▪ Rationale for not tapering and discontinuing opioid. ▪ Patient has a pain management/opioid agreement with the prescriber. ▪ Patient has/will have random urine drug screens as part of their on-going therapy with opioids. ▪ If patient is concurrently on a CNS depressant (e.g., benzodiazepines), prescriber has reviewed and will address the increased risk with respiratory depression with the patient. ▪ Patient has screened for depression or other mental health illness.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA CRITERIA • If patient is positive for depression, patient is receiving either pharmacological or nonpharmacological treatment. o Patient has been screened for substance abuse/opioid dependence. o If dose exceeds 90 MME per day, prescriber must attest to one of the following: ▪ Dose reduction has occurred since previous approval. ▪ Documentation that a dose taper has been attempted within the past 6 months and was not successful. o If request is for a long-acting opioid, must meet the following: ▪ Patient must have a documented history of failure, contraindication or intolerance to a trial of at least two preferred short-acting opioids. ▪ Patient must have received a short-acting opioid for greater than 30 days in the last 60 days. ▪ Trial and failure of at least two preferred long-acting opioids are required before the use of a non-preferred unless there is intolerance or contraindications. • If none of the above criteria are met, a one-time, one-month override is allowed for tapering. **Initial Approval Duration:** 3 months • Renewal Authorization Criteria for Chronic Pain o All narcotic analgesics are written by a single KMAP-enrolled prescriber or practice. o Documentation of treatment duration and treatment goals. o Prescriber provides rationale supporting inability to taper or discontinue opioid therapy. o Patient will not be maintained on more than one long-acting & one short-acting opioid analgesics, concurrently. o Patient has a pain management/opioid agreement with the prescriber (excluding patients in a long-term care facility). o Prescriber has reviewed controlled substance prescriptions in PDMP (KTRACS). o Patient has/will have random urine drug screens as part of their on-going therapy with opioids (excluding patients in a long-term care facility) o If the current dose exceeds 90 MME/day, one of the following criteria must be met: ▪ Dose reduction has occurred since previous approval; ▪ Documentation that a dose taper has been attempted within the past 6 months and was not successful. **Renewal Approval Duration:** 12 months **NOTES:** **GENERAL CRITERIA FOR OPIOID MEDICATION USE:** • Initial use max of 7-day fills (cumulative 14 day supply in 60 days) is allowed before PA will be required. • Ninety percent (90%) of medicine must be used prior to a refill unless a PA for early refill is approved. • Prescriber must attest to reviewing K-TRACS prior to writing every new opioid prescription. • Prescriber should calculate total MME per day for concurrent opioid medications. • Initial use of immediate-release opioids is required before use of ER/LA opioids. • Provider attests to limiting and avoiding where possible the concurrent use of CNS depressants, especially benzodiazepines, when prescribing opioids. • Before starting & periodically, an evaluation of risk factors for opioid related harms should be done. • Non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) and non-pharmacological treatments should be tried first unless contraindicated. • Prescriber has screened patient for depression and substance use disorder. • New dosage forms or strengths to agents listed can be added as they become available. • Drug must not exceed maximum FDA approved dosage. • Physician must consider use of opioids and Neonatal Opioid Withdrawal Syndrome if patient is pregnant. **Public Comment:** None. **Board Discussion:**	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Defined criteria #2 by adding 'for acute pain' and defined criteria #3 by adding 'for chronic pain'.	
C. Revised Prior Authorization (PA) Criteria 10. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor Combinations i. Revised PA Criteria	**Background:** The SGLT2 inhibitor combinations prior authorization criteria was last revised in January 2018. This revision had a typographical error during approval which has since been corrected. Also since that time, the FDA has approved two new SGLT2 inhibitor products, Steglujan and Segluromet. The criteria is being revised to correct the error, include the new products, have consistent wording for required previous medication trials, and ensure appropriate use. APPROVED PA Criteria Initial Approval: April 8, 2015 Revised Date: April 11, 2018; January 10, 2018; October 11, 2017; April 12, 2017; October 12, 2016; July 13, 2016 **CRITERIA FOR PRIOR AUTHORIZATION** Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor Combinations **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Canagliflozin/metformin (Invokamet®, Invokamet XR®) Dapagliflozin/metformin (Xigduo XR®) Dapagliflozin/saxagliptin (Qtern®) Empagliflozin/linagliptin (Glyxambi®) Empagliflozin/metformin (Synjardy®, Synjardy XR®) Ertugliflozin/sitagliptin (Steglujan™) Ertugliflozin/metformin (Segluromet™) **CRITERIA FOR PRIOR AUTHORIZATION FOR SGLT2 INHIBITOR COMBINATIONS:** (must meet all of the following) • Patient must have a diagnosis of type II diabetes • Patient MUST NOT have a diagnosis of type I diabetes • Patient must be 18 years of age or older • Patient must have an eGFR above: o 45 mL/min/1.73m^2 (Glyxambi, Invokamet, Invokamet XR, Synjardy, Synjardy XR, Qtern) o 60 mL/min/1.73m^2 (Xigduo XR, Steglujan, Segluromet) • Patient MUST NOT have any of the following contraindications: o End-stage renal disease o Currently on dialysis • Patient must have experienced an inadequate response after a trial of a preferred metformin ER agent at a maximum tolerated dose, OR have a documented intolerance or contraindication to metformin ER **LENGTH OF APPROVAL:** 12 months **Public Comment:** None.	Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Board Discussion: None.	
C. Revised Prior Authorization (PA) Criteria 11. Topical Acne Medications i. Revised PA Criteria	**Background:** Prior authorization criteria for Topical Acne Medications were last revised in January 2016. The prior authorization criteria is being revised to remove criteria for Finacea for rosacea as more current criteria for this product is included in the rosacea prior authorization criteria.  APPROVED PA Criteria Initial Approval: June 15, 2011 Revised Date: April 11, 2018; January 13, 2016; October 8, 2014; July 11, 2012 CRITERIA FOR PRIOR AUTHORIZATION Topical Acne Agents PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: All dosage forms of the following drugs require prior authorization: Adapalene (Differin®) Adapalene/Benzyl Peroxide (Epiduo®, Epiduo Forte®) Azelaic Acid (Azelex®) Dapsone (Aczone®) Tretinoin (Retin-A®, Atralin®, Tretin-X®, Avita®) Tretinoin Microspheres (Retin-A Micro®) Tretinoin/Clindamycin (Veltin®, Ziana®) Tazarotene (Tazorac®, Fabior®) CRITERIA FOR ACNE VULGARIS: (must meet all of the following) • Patient must have a diagnosis of acne vulgaris • For Epiduo and Epiduo Forte, patient must be 9 years of age or older • For Atralin, patient must be 10 years of age or older • For all other acne products, patient must be 12 years of age or older CRITERIA FOR PLAQUE PSORIASIS (TAZORAC ONLY): (must meet all of the following) • Patient must have a diagnosis of plaque psoriasis • For Tazorac 0.05% and 0.1% **cream**, patient must be 18 years of age or older • For Tazorac 0.05% and 0.1% **gel**, patient must be 12 years of age or older LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** None.	Dr. Backes moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
C. Revised Prior Authorization (PA) Criteria	**Background:** Verzenio is a cyclin-dependent kinase (CDK) inhibitor, indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative	Dr. Heston moved to approve. Dr. Backes seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
12. Verzenio™ (abemaciclib) i. Revised PA Criteria	advanced or metastatic breast cancer in women with disease progression following endocrine therapy. Prior authorization criteria was initially approved in January 2018. Since that time, Verzenio has been FDA-approved for use as initial endocrine based therapy, in combination with an aromatase inhibitor, for HR positive HER2 negative advanced or metastatic breast cancer in postmenopausal women. The criteria is being revised to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.	The motion was approved unanimously.
C. Revised Prior	**Background:**	Dr. Kollhoff moved to approve.

APPROVED PA Criteria

Initial Approval: January 10, 2018
Revised Dates: April 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Abemaciclib (Verzenio™)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES All dosage forms of the following drugs require prior authorization:
Abemaciclib (Verzenio™)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have a diagnosis of advanced or metastatic breast cancer
- The tumor must be hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative
- Must be prescribed by or in consultation with an oncologist
- Patient must be 18 years of age or older
- Patient must not be pregnant or breastfeeding and be advised to not become pregnant for at least 3 weeks after the last dose
- For use as initial endocrine based therapy (must meet all of the following):
  - Medication is being used in combination with an aromatase inhibitor
  - Patient must be postmenopausal
- Patients that have experienced disease progression following endocrine-based therapy must meet one of the following:
  - Patient is postmenopausal and will be using the medication in combination with fulvestrant
  - Patient is pre- or perimenopausal and will be using the medication in combination with fulvestrant and a gonadotropin releasing hormone agonist
  - Medication is being used as monotherapy and patient has experienced disease progression following prior chemotherapy in the metastatic setting of breast cancer
- Dose does not exceed FDA approved maximum dosing limits:
  - Monotherapy: 200 mg twice daily
  - Combination therapy: 150 mg twice daily

LENGTH OF APPROVAL: 12 months

Notes:

- When co-administered with fulvestrant, recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29; and once monthly thereafter.
- Gonadotropin releasing hormone agonists used in breast cancer: Lupron (leuprolide) and Zoladex (goserelin).

Public Comment:
None.

Board Discussion:
None.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Authorization (PA) Criteria 13. Xgeva® (denosumab) i. Revised PA Criteria	Xgeva is approved for the prevention of skeletal-related events in patients with bone metastases from solid tumors, and the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Prior authorization criteria were first approved in October 2013. Since that time, Xgeva has become indicated for the use in the treatment of hypercalcemia of malignancy and multiple myeloma. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. APPROVED PA Criteria Initial Approval: October 9, 2013 Revised Dates: April 11, 2018 CRITERIA FOR PRIOR AUTHORIZATION Denosumab (Xgeva®) PROVIDER GROUP: Pharmacy Professional MANUAL GUIDELINES: All dosage forms of the following drugs require prior authorization; Denosumab (Xgeva®) CRITERIA FOR BONE METASTASES FROM SOLID TUMORS (Must meet all of the following): • Patient must have bone metastases from a solid tumor • Patient must be 18 years of age or older • Patient must not be receiving Prolia concurrently CRITERIA FOR GIANT CELL TUMOR OF BONE (Must meet all of the following): • Patient must have giant cell tumor of bone • Patient must be 13 years of age or older • Patients aged 13-17 years of age must meet the following: o Patient must have reached skeletal maturity, defined by at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) o Patient must have reached a body weight of ≥ 45 kg • Patient must not be receiving Prolia concurrently CRITERIA FOR HYPERCALCEMIA OF MALIGNANCY (Must meet all of the following): • Patient must have a diagnosis of hypercalcemia of malignancy that is refractory to bisphosphonate therapy • Patient must be 18 years of age or older • Patient must not be receiving Prolia concurrently CRITERIA FOR MULTIPLE MYELOMA (Must meet all of the following): • Patient must have a diagnosis of multiple myeloma • Patient must be 18 years of age or older • Patient must not be receiving Prolia concurrently LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** None.	Dr. Heston seconded the motion. The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 1. Anti-emetics - Cannabinoids	**Background:** This criteria will combine and supersede all previous criteria for past cannabinoid agents including dronabinol agents and Cesamet. The prior authorization criteria are being proposed	Dr. Backes moved to approve. Dr. Heston seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
i. Prior Authorization Criteria	to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	The motion was approved unanimously.

APPROVED PA Criteria

Initial Approval: April 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Anti-emetics - Cannabinoids

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES All dosage forms of the following drugs require prior authorization:
Dronabinol (Marinol®, Syndros®)
Nabilone (Cesamet®)

*** This criteria combines and supersedes all previously approved criteria for the above listed products****

CRITERIA FOR PRIOR AUTHORIZATION: (must meet all of the following)

- Patient must have one of the following diagnoses and meet all of the corresponding criteria relating to that diagnosis:
  - Intractable nausea and vomiting associated with cancer chemotherapy, AND
    - Patient must have experienced an inadequate response after a trial of conventional antiemetic treatment (i.e.5-HT3 receptor antagonists, Anticholinergics, Antidopaminergics, etc.) at a maximum tolerated dose, OR have a documented intolerance or contraindication to the conventional antiemetic treatments.
    - Must be prescribed by or in consultation with an oncologist
  - Anorexia associated with weight loss in patients with AIDS (**Dronabinol (Marinol®, Syndros®) only),** AND
    - Must be prescribed by or in consultation with an HIV specialist
- Dose must fall within the below dosing limitations:
  - **Dronabinol (Marinol®, Syndros®):** less than or equal to 30mg/day
  - **Nabilone (Cesamet®):** less than 6 mg per day

CRITERIA FOR RENEWAL: (must meet one of the following)

- Patients with a diagnosis of AIDS wasting must have maintained or increased BMI compared to baseline
- Patients with nausea associated with cancer chemotherapy must have experienced a reduction in the frequency or severity of nausea associated with cancer chemotherapy

LENGTH OF APPROVAL 6 months

Public Comment:
None.
Board Discussion:
None.

D. New Prior Authorization (PA) Criteria 2. Anti-emetics - NK-1	**Background:** This criteria will combine and supersede all previous criteria for past NK-1 antagonists and NK1 combination products. The prior authorization criteria are being proposed to ensure	Dr. Heston moved to approve. Dr. Rice seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
antagonists and NK1 combinations i. Prior Authorization Criteria	appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. APPROVED PA Criteria Initial Approval: April 11, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Anti-emetics: Neurokinin 1 (NK-1) Antagonists/NK-1 Antagonist Combinations **PROVIDER GROUP** Pharmacy Professional **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Aprepitant (Emend® oral, Cinvanti™) Fosaprepitant (Emend® IV) Netupitant/palonosetron (Akynzeo®) Rolapitant (Varubi®) *** This criteria combines and supersedes all previously approved criteria for the above listed products*** **CRITERIA FOR PRIOR AUTHORIZATION FOR PREVENTION OF NAUSEA/VOMITING ASSOCIATED WITH CHEMOTHERAPY:** (must meet all of the following) • Patient must have a diagnosis of cancer • Patient must be on oral or intravenous (IV) chemotherapy **LENGTH OF APPROVAL:** 12 months **CRITERIA FOR PRIOR AUTHORIZATION FOR PREVENTION OF POSTOPERATIVE NAUSEA/VOMITING:** (must meet all of the following) • Request must be for oral aprepitant (Emend®) • Must be used for prevention of postoperative nausea and vomiting (PONV) • MUST NOT be used for treatment of PONV **LENGTH OF APPROVAL:** 1 capsule for 1 fill **Public Comment:** None. **Board Discussion:** None.	The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 3. Glucagon-Like Peptide (GLP-1) Receptor Agonists i. Prior Authorization Criteria	**Background:** GLP-1 receptor agonists are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. This criteria will combine and supersede all previous criteria for past PAs for all GLP-1 receptor agonists. The prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information, consolidate criteria, and to be consistent with similar agents.	Dr. Rice moved to approve as amended. Dr. Unruh seconded the motion. The criteria was approved as amended unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: April 11, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** GLP-1 Receptor Agonists **PROVIDER GROUP:** Pharmacy **MANUAL GUIDELINES:** All dosage forms of the following drugs require prior authorization: Albiglutide (Tanzeum®) Dulaglutide (Trulicity®) Exenatide (Byetta®) Exenatide ER (Bydureon®, Bydureon® BCise™) Liraglutide (Victoza®) Lixisenatide (Adlyxin™) Semaglutide (Ozempic®) *** This criteria combines and supersedes all previously approved criteria for the above listed products**** **CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS:** (must meet all of the following) • Patient must be at least 18 years old. • Patient must have a diagnosis of Type 2 Diabetes. • Patient must have HbA1c above 6.5% • Patient must have experienced an inadequate response after a trial of a preferred metformin ER agent at a maximum tolerated dose, OR have a documented intolerance or contraindication to metformin ER. • • **Additional Criteria for Bydureon®, Bydureon BCise®, Byetta®, Ozempic®, Tanzeum®, Trulicity®, and Victoza®** o Patient must not have history or family history of medullary thyroid carcinoma in the past 2 years. o Patient must not have history of multiple endocrine neoplasia syndrome type 2 in the past 2 years. **CRITERIA FOR RENEWAL FOR ALL PRODUCTS:** (must meet one of the following) • Documented improvement of HbA1c from pretreatment levels • Achievement or maintenance of therapeutic goals (HbA1c ≤ 6.5%) **LENGTH OF APPROVAL:** 12 months **Public Comment:** Jason Lark with Novo Nordisk spoke on behalf of Ozempic®. **Board Discussion:** Length of approval amended to read 12 months.	
D. New Prior Authorization (PA) Criteria 4. Luxturna® (voretigene neparvovec-rzyl)	**Background:** Luxturna is an adeno-associated virus vector-based gene therapy, indicated for the treatment of retinal dystrophy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.	Dr. Backes moved to approve. Dr. Unruh seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Prior Authorization Criteria	APPROVED PA Criteria Initial Approval: April11, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Voretigene neparvovec-rzyl (Luxturna™) **PROVIDER GROUP** Professional **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Voretigene Neparvovec-rzyl (Luxturna™) **CRITERIA FOR PRIOR AUTHORIZATION:** (must meet all of the following) • Patient must have a diagnosis of retinal dystrophy • The patient's retinal dystrophy must be associated with a biallelic RPE65 mutation, as confirmed by an FDA-approved test o Documentation of genetic testing confirming the presence of a bilallelic RPE65 mutation must be provided • Patient must have sufficient viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy. Must have one of the following: o An area of retina within the posterior pole of >100 microns thickness (shown on OCT); o ≥3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole; or o Remaining visual field within 30◦ of fixation as measured by III4e isopter or equivalent • Patient must be 1 year of age or older • Must be prescribed by or in consultation with an ophthalmologist • Patient has not received prior RPE65 gene therapy in intended eye • If both eyes are to be treated, the initial eye's injection and the second eye's injection must be administered at least 6 days apart **LENGTH OF APPROVAL** One time approval (1 injection per eye) **Public Comment:** None. **Board Discussion:** None.	The motion was approved unanimously.
D. New Prior Authorization (PA) Criteria 5. Yescarta® (axicabtagene ciloleucel) i. Prior Authorization Criteria	**Background:** Yescarta is a T cell immunotherapy, indicated for the treatment of relapsed or refractory large B-cell lymphoma. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.	Dr. Backes moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: April 11, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Axicabtagene Ciloleucel (Yescarta™) **PROVIDER GROUP** Professional **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Axicabtagene Ciloleucel (Yescarta™) **CRITERIA FOR PRIOR AUTHORIZATION:** (must meet all of the following) • The patient must have a diagnosis of relapsed or refractory large B-cell lymphoma of one of the following types: o Primary mediastinal large B-cell lymphoma o High-grade B-cell lymphoma o Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma o DLBCL not otherwise specified • The patient must not have primary CNS lymphoma • The patient must have previously experienced treatment failure with 2 or more lines of systemic therapy • The patient must be 18 years of age or older • Must be prescribed by, or in consultation with, an oncologist or hematologist • The patient must not have any active infection or active inflammatory process • The patient must meet the following (if applicable): o Females: not be pregnant (verified negative pregnancy test prior to initiating treatment for those of reproductive potential) and be advised to not become pregnant during treatment • The patient must be receiving the medication from a healthcare facility that is enrolled and in compliance with the Yescarta REMS requirements • The patient has not received prior CAR-T therapy • Dose must not exceed the recommended dose based on weight (below) o 2 x 10^8 chimeric antigen receptor (CAR)-positive viable T cells **LENGTH OF APPROVAL** 12 months **Public Comment:** Parvoneh Navas with Kite/Gilead spoke on behalf of Yescarta®. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 6. Proton Pump Inhibitor (PPI) i. Prior Authorization Criteria	**Background:** PPIs are indicated for the treatment of multiple GI disorders related to ulceration and acid production. Prior authorization criteria is being introduced to include step-therapy requirements.	Dr. Heston moved to approve. Dr. Backes seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: April 11, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Proton Pump Inhibitor (PPI) Step Therapy **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** All dosage forms of the following drugs require prior authorization: Rabeprazole (AcipHex® Sprinkles™) Dexlansoprazole (Dexilant® SoluTab) Esomeprazole (Nexium ®Suspension) Lansoprazole (Prevacid SoluTab®) Omeprazole (Prilosec® Packets) Omeprazole/sodium bicarbonate (Zegerid®) Omeprazole/sodium bicarbonate (Zegerid® Packets) Pantoprazole (Protonix® Packets) **CRITERIA FOR PRIOR AUTHORIZATION APPROVAL:** • The following criteria will apply for the use of alternate dosage forms, such as suspensions, granule packets and oral dissolvable formulations (must meet one of the following): o Infants, 1 month to 1 year of age will be granted approval for Prilosec oral suspension (packets) or Nexium oral suspension (packets); both indicated for use down to 1 month of age o Patient must have a documented trial and failure of or contraindication (i.e. feeding tube, dysphagia) to opening an equivalent capsule dosage form (if available) and mixing/sprinkling the contents of the capsule into applesauce for administration • Zegerid o Patient must have experienced an inadequate response after a 90 consecutive day trial of omeprazole at an equivalent dose in the past 120-days, OR have a documented intolerance or contraindication to omeprazole. **LENGTH OF APPROVAL:** 12 months **Public Comment:** None. **Board Discussion:** None.	
E. Mental Health Medication Advisory Committee (MHMAC) 1. Adult Antipsychotic Dosing Limits i. Prior Authorization	**Background:** At the February 2018 MHMAC meeting, the criteria was amended for a title change from "16 and Older Antipsychotic Dosing Limits" to "18 and Older Antipsychotic Dosing Limits". The revised criteria also have added medications included in this criteria and an initial written peer-to-peer consultation option.	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Criteria	PA Criteria Initial Approval: January 13, 2016 Revised Dates: April 11, 2018; April 12, 2017 **CRITERIA FOR PRIOR AUTHORIZATION** 18 and Older Antipsychotic Dosing Limits **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drugs require no prior authorization up to the maximum daily dose listed below: Aripiprazole (Abilify®, Abilify Maintena®, Aristada®) Asenapine (Saphris®) Brexpiprazole (Rexulti®) Cariprazine (Vraylar®) Chlorpromazine Clozapine (Clozaril®, Fazaclo®, Versacloz®) Fluphenazine Haloperidol (Haldol®, Haldol® Decanoate) Iloperidone (Fanapt®) Loxapine (Adasuve®, Loxitane®) Lurasidone (Latuda®) Molindone Olanzapine (Zyprexa®, Zyprexa Zydis®, Zyprexa Relprevv®) Olanzapine/Fluoxetine (Symbyax®) Paliperidone (Invega®, Invega Sustenna®, Invega Trinza®) Perphenazine Pimozide (Orap®) Prochlorperazine (Compazine®, Compro®) Quetiapine (Seroquel®, Seroquel XR®) Risperidone (Risperdal®, Risperdal Consta®, Risperdal M-Tab®) Thioridazine Thiothixene Trifluoperazine Ziprasidone (Geodon®) **CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIPSYCHOTIC DOSING LIMITS:** • Doses exceeding those listed in Table 1 will require a prior authorization o Prior authorization will require a written peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer, if unable to approve written request. **LENGTH OF APPROVAL:** 12 months **Public Comment:** None. **Board Discussion:** None.	
E. Mental Health Medication Advisory Committee (MHMAC)	**Background:** At the February 2018 MHMAC meeting, committee approved dosing limitation criteria for use of oral benzodiazepines in patients over 18 years of age. These patients receiving an oral	Dr. Backes moved to approve. Dr. Heston seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
2. ORAL Benzodiazepine Dosing Limits for ≥18 Years of Age i. Prior Authorization Criteria	benzodiazepine at a dose greater than that listed in the criteria will require prior authorization that ensures safe and appropriate use.	The motion was approved unanimously.

Initial Approval: April 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

ORAL Benzodiazepine Dosing Limits for ≥18 Years of Age

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drugs require prior authorization:

Alprazolam (Xanax®, Xanax XR®, Alprazolam Intensol®, Niravam ODT®)
Chlordiazepoxide (Librium®)
Clonazepam (Klonopin®)
Clorazepate (Tranxene-T®)
Diazepam (Valium, Diazepam Intensol®)
Estazolam (ProSom®)
Flurazepam (Dalmane®)
Lorazepam (Ativan®, Lorazepam Intensol®)
Oxazepam (Serax®)
Quazepam (Doral®)
Temazepam (Restoril®)
Triazolam (Halcion®)

*Onfi® is not included in this PA criteria due to its current exclusive use as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years and older.

CRITERIA FOR PRIOR AUTHORIZATION FOR BENZODIAZEPINE DOSING LIMITS

- Doses exceeding those listed in Table 1 will require a prior authorization
  - Prior authorization will require a written peer-to-peer review with the health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer, if unable to approve written request.
  - Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program (PDMP) a.k.a K-TRACS.
  - If patient is concurrently on a CNS depressant (e.g., opioid), prescriber has reviewed and will address the increased risk of respiratory depression with the patient.

LENGTH OF APPROVAL: 12 Months

RENEWAL CRITERIA: Patient is stable and has been seen in the past year.

Public Comment:
None.
Board Discussion:
None.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
IV. Open Public Comment:	None.	
V. Adjourn:		Dr. Mittal adjourned the April 11, 2018 DUR Meeting at 12:43pm.
The next DUR Board meeting is scheduled for July 11, 2018. Public Comment: is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.		